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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/896,278	06/29/2001	Gilbert Lavielle	ADIR360/lw	7985

7590 03/19/2003

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EXAMINER

BERNHARDT, EMILY B

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 03/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/896,278

Applicant(s)  
Lavielle et al.

Examiner  
Emily Bernhardt

Art Unit  
1624



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 1/13/03 and 1/15/03.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 18-26, 28, 29, and 32-34 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18-26, 28, 33, and 34 is/are rejected.
- 7) ☒ Claim(s) 29 and 32 is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 10 6) ☐ Other:

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In view of applicants' reponse of 1/13/03 and supplemental response of 1/15/03 the following still applies.

Applicant's election of II in Paper No. 7 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Receipt of new abstract is acknowledged.

Claims 18-26,28,33 and 34 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Reason #1 of the previous action remains. The tropone ring relied <sup>on</sup> ~~in~~ by applicants isnt even covered by the claim language. The 7-membered rings in the claims must be heteroaromatics. The tropone ring is carbocyclic.

2. In view of applicants amendment deleting nonelected subject matter the "G3" designation should be deleted since it may be construed as an additional variable on the piperazine ring rather than as formula G3.

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**Claims 18-26,28,33-34 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.**

**1.The how to use rejection (#1) remains for the scope of R-fused ring systems other than phenyl and for the scope of X-fused ring systems that can be from 5- to 7-membered and have up to 2 N and/ or O atoms in any array. Examples in the specification support C4-C7 cycloalkyl which can be interrupted by 1 N or O atom. Limiting to the aforementioned scope at the R- and X-ring systems would overcome this rejection. Applicants' response to the rejection under par.two does not. Other than the examples pointed out in the previous action there is no guidance what other ring systems would have the dual action of activity relied on to practice the invention.**

**2. Method claim 33 remains rejected despite the presentation of specific uses. The references listed in the Declaration filed 1/13/03 are only persuasive for treating Parkinson's Disease based on the Fox reference and treating**

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impulsive behaviour disorders based on the statement made by declarant regarding test C in the declaration. Treating anxiety and depression, which was indicated in previous action as correlated to 5-HT<sub>2c</sub> antagonism also would not be objected to. However, remaining scope of disorders are rejected. References Berendsen (#1) and Millan (#2) (1997) listed in the IDS deal with inhibiting drug-induced penile erection in rats employing various 5-HT antagonists which appears to be relied on as a useful screening tool for characterizing novel compounds at various 5-HT sites. Reference 3 also by Millan deals with one lead compound having been tested for antidepressant activity in various animal models. Shih, reference 4, deals with treating aggression based on 5-HT<sub>2A</sub> receptor binding. Applicants stated their compounds have combined activity as  $\alpha$ -2 adrenergic and 5-HT<sub>2c</sub> antagonists. Reference 5 deals with impulsive disorders not rejected for reason given above. References 6 and 8-10 deal either with Parkinson's or depression, uses not rejected. Reference #7 by Smith appears to be relied on for treating any and all <sup>cognitive</sup> ~~negative~~ disorders but Smith at best shows for 1  $\alpha$ -2 antagonist improvement in only one aspect<sup>t</sup> of attention as discussed in the abstract and

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**body of the article. References 11-16 deal with treating side effects associated with classical neuroleptics vs atypical drugs such as clozapine. While there is mention of the activities relied on herein there are many different hypotheses as outlined in Nutt and the other references and to actually treat schizophrenia and reduce the side effects such as extrapyramidal symptoms the references all discuss compounds that have activity at the dopamine receptor as well. There is no mention that instant compounds are dopamine active. Lane the last reference cited while dealing with various types of sexual dysfunction linked to known antidepressants such as SSRI's has only one mention of a compound that has  $\alpha_2$ -adrenoreceptor activity as discussed on p.78. The compound at low doses is postulated in alleviating only one type of sexual dysfunction and this only in low doses. At higher doses it has been found to also cause sexual dysfunction. Instant compounds are antidepressants as well and specifically tested to inhibit (not promote) penile erection. There is otherwise no dosage information regarding its selective use to treat any type of sexual dysfunction discussed by Lane.**

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**The art rejections of the previous action are overcome in view of the narrowing at instant T3.**

**Claims 29 and 32 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.**

**THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).**

**A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.**

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Any inquiry concerning this communication should be directed to Emily Bernhardt at telephone number (703) 308-4714.

A facsimile center has been established for Group 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703) 308-4556 or (703) 305-3592.

*E Bernhardt*

**EMILY BERNHARDT**

**PRIMARY EXAMINER**

**GROUP 1600**